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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,984	05/25/2006	Curtis Dobson	81599-002US0	5866

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
12/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/580,984	DOBSON, CURTIS	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,10,11,13,14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) *10,11,13,14,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,7,8 and 18* is/are rejected.

7)☒ Claim(s) *3 and 4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on October 28, 2010 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 1-5, 7, 8, 10, 11, 13, 14 and 16-18 are pending.

Applicants' amendment filed October 28, 2010 is acknowledged. Applicants' response has been fully considered. Claims 1, 3, 4, 7 and 16 have been amended, and claim 6 has been cancelled. Claims 10, 11, 13, 14, 16 and 17 are non-elected inventions and are withdrawn from consideration. Therefore, claims 1-5, 7, 8 and 18 are examined.

Withdrawn Informalities

3. The previous objection to the specification regarding Sequence Listing is withdrawn in view of applicants' submission of a new version of Sequence Listing, and applicants' response at page 7 in the amendment filed October 28, 2010. CRF has been entered.

Withdrawn Claim Objections

4. The previous objection to claims 3 and 7 is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 7 in the amendment filed October 28, 2010.

Withdrawn Claim Rejections - 35 USC § 112

5. The previous rejection of claims 3, 4, 6 and 7 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claims, and applicants' response at pages 7-8 in the amendment filed October 28, 2010.

Withdrawn Claim Rejections - 35 USC § 102

6. The previous rejection of claims 1, 3-4 and 8 under 35 U.S.C. 102(b) as being anticipated by Lunec *et al.* (WO 98/42751) is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 8-9 in the amendment filed October 28, 2010.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-2, 5, 8 and 18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-2, 5, 8 and 18 are directed to a polypeptide, derivative or analogue thereof, comprising a tandem repeat of apolipoprotein B, wherein the isolated polypeptide, derivative or analog thereto is according to formula I: abcRKRxyza'b'c'RKRx'y'z' (I) or a truncation thereof comprising the tandem repeat of apolipoprotein B, characterized in that the tandem repeat or truncation thereof is obtained from an HSPG receptor binding region of apolipoprotein B; and a composition comprising the polypeptide, derivative or analogue thereof.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other

materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification discloses that GIN16 (SEQ ID NO:48) has antiviral effect against HSV1 and some peptides comprising a tandem repeat from an HSPG receptor binding region of apolipoprotein B exhibit antiviral properties (pages 5-6, 11-12), the specification does not disclose a genus of variants for polypeptides, derivatives or analogues comprising a tandem repeat of apolipoprotein B and being the formula (I), or a truncation thereof, where the tandem repeat or truncation thereof is obtained from an HSPG receptor binding of apolipoprotein B, where the correlation between structure and function of the peptide variants is not indicated. The specification does not sufficiently describe the whole genus of peptide variants when there is substantial structural variation (e.g., a and a', c and c', x and x', y and y', z and z' being a positively charged residue, which may be R, K or H) within the genus with no defined function. Some species of antiviral peptides (listed on pages 11-12) do not provide sufficient written description for the whole genus of peptide variants obtained from an HSPG receptor binding of

apolipoprotein B and including numerous analogs, derivatives and truncations with no defined structure/function correlation. Without guidance on structure to function/activity of various peptides (e.g., formula I) obtained from an HSPG receptor binding of apolipoprotein B, one skilled in the art would not readily identify a functional peptide. The lack of a structure to function/activity relationship for the peptide variants obtained from an HSPG receptor binding of apolipoprotein B, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Response to Arguments

Applicants indicate that claim 1 has been amended to recite that the isolated polypeptide, derivative or analogue thereof is according to formula I with different positions defined in the same manner as in cancelled claim 6. As previously discussed, the specification provides sufficient detail to convey to one of ordinary skill in the art that applicant had possession of the claimed invention. For example, the specification describes 20 different peptides (listed on pages 11-12). Additionally, the specification provides a definition, by structure and formula (formulas I, II, III and IV) that is sufficient to distinguish it from other materials. The claims, as amended, clarify that the derivative, analogue and truncation will still have the tandem repeat. As explained throughout the specification (e.g., page 6, first and third full paragraph), polypeptides having the tandem repeat region derived from an HSPG receptor binding region of apolipoprotein B exhibited antiviral properties. Thus, the tandem repeat is the defined structure that is correlated with the antiviral function of the polypeptide, derivative, analogue, and truncation. The combination of this disclosure clearly conveys to one of ordinary

skill in the art that Applicant had possession of the claimed invention at the time of the filing of the application. In light of the foregoing, Applicants request reconsideration and withdrawal of this rejection (pages 7-8 of the response).

Applicants' response has been fully considered. Regarding claims 3, 4 and 7, the arguments are found persuasive and the rejection is withdrawn. However, regarding claims 1-2, 5, 8 and 18, the arguments are not found persuasive because of the following reasons. While the specification discloses 20 different peptides ranging from 14 to 18 amino acids (at pages 11-12) and formulas I, II, III or IV (pages 9-11), the whole genus of claimed peptide variants according to formula I without structure and function correlation would encompass numerous peptides with substantial structural variations, e.g., a and a', c and c', x and x', y and y', z and z' being a positively charged residue, which may be R, K or H in formula I. Without structure/function correlation of peptide variants, one skilled in the art cannot readily identify a functional peptide. For these reasons, applicants are not in possession of the claimed invention, and the rejection is maintained.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 2, 5, 7, 8 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 1, 2, 5, 8 and 18 are indefinite as to the term "selected from the group consisting of a positively charged residue, which may be Arginine (R), Lysine (K) or Histidine (H)". It is

unclear what are the metes and bounds for a positively charged residue. Since the claim recites a positively charged residue may be R, K or H, thus, if the positively charged residue were not R, K or H, what residues the positively charged residue is. Claims 2, 5, 8 and 18 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

10. Claims 5 and 18 are indefinite because claim 5 or 18 does not further limit the claim (i.e., claim 3 or 4) from which it depends. Claim 3 (or claim 4) is directed to the peptide, derivative, or analog thereof comprising a tandem repeat of human apolipoprotein $B_{(3359-3367)}$ having amino acid sequence SEQ ID NO:1 or truncation thereof comprising the tandem repeat (or comprising a tandem repeat of the amino acid sequence of SEQ ID NO:1 for claim 4), claim 3 does not comprise a tandem repeat of the amino acid sequence of SEQ ID NO:1 being substituted, and claim 4 does not comprise a tandem repeat of the amino acid sequence of SEQ ID NO:1 being substituted or deleted.

11. Claim 7 recites the limitation "comprising the amino acid sequence" in line 2. There is insufficient antecedent basis for this limitation in the claim (claim 1). Claim 1 recites "wherein the isolated polypeptide, derivative or analog thereto is according to formula I: abcRKRxyza'b'c'RKRx'y'z' (I) or a truncation thereof".

Claim Objections

12. Claims 3 and 4 are objected to because the claim depends from a rejected claim.

Conclusion

13. Claims 1, 2, 5, 7, 8 and 18 are rejected; claims 3 and 4 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached at 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
November 29, 2010